510(k) Summary

APR 2 4 2006

Modified Indication for Use for IVA

Submitter:	Hologic, Inc.
Submitter Address:	35 Crosby Drive Bedford, MA 01730
Contact Person:	Jeanette Schier-Pugsley, Regulatory Affairs Manager
Phone Number:	(781) 999-7406
Fax:	(781) 280-0614
Date of Submission:	January 13, 2006
Device Trade Name:	IVA (MXA –II) software option for the X-Ray bone densitometers.
Device Common Name:	X-Ray Bone Densitometer
Device Classification:	Bone Densitometer 21 CFR 892.1170
Predicate Devices:	Hologic Vertebral Morphometry Software Option (K941362) Hologic Vertebral Morphometry Software II Option (K992775) General use x-ray systems (*e.g.*, Toshiba KXO-80G x-ray generator; K945668)
Device Description and Intended Use:	IVA scans are intended for the visualization or quantitative assessment of vertebral bone deformities. IVA also allows the visualization of abdominal aortic calcification, and, if present, clinical correlation may be advised since abdominal aortic calcification may be associated with cardiovascular disease.
Substantial Equivalence:	No changes to the manner in which the MXA or MXA-II software operates will be made for the modification to the intended use, nor will any changes be made in the device's performance specifications. The modified intended use statement of the presently commercialized Hologic MXA-II software option is substantially equivalent to those of the MXA-II and MXA software options (K992775 and K941362,

respectively), and that of general diagnostic x-ray systems, such as the Toshiba KXO-80G x-ray generator (K945668). Clinical data presented in the submission support the new claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 2 4 2006

Ms. Jeanette Schier-Pugsley, RAC
Regulatory Affairs Manager
Hologic, Inc.
35 Crosby Drive
BEDFORD MA 01730

Re: K060111
Trade/Device Name: IVA (MXA II Software Option)
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: KGI
Dated: April 3, 2006
Received: April 4, 2006

Dear Ms. Schier-Pugsley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K060111

Device Name: IVA (MXA II Software Option)

Indications for Use:

IVA scans are intended for the visualization or quantitative assessment of vertebral bone deformities. IVA also allows the visualization of abdominal aortic calcification, and, if present, clinical correlation may be advised since abdominal aortic calcification may be associated with cardiovascular disease.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use

(Per 21 CFR 801.109) (Optional Format 1)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060111